



Application for

Continuation of an Individual National Research Service Award

PHS 416-9

Public Health Service

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Individual National Research Service Award Continuation Application Form PHS 416-9

*PHS estimates that it will take approximately 7 hours to complete this application. This estimate does not include time for development of the research training plan. Items such as human subjects are cleared and accounted for separately, and are therefore also not part of the time estimate for completing this form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send comments to: NIH, Project Clearance Office, 6701 Rockledge Drive MSC 7730, Bethesda, MD 20892-7730, Attention: PRA (0925-0002). **DO NOT RETURN THE COMPLETED FORM TO THIS ADDRESS.***

I. SUBMITTING YOUR APPLICATION

Applications to continue previously recommended support of an Individual National Research Service Award (NRSA) Fellowship Award from the National Institutes of Health (NIH) or the Agency for Health Care Policy and Research (AHCPR), must be submitted (on PHS 416-9) 2 months before the beginning date of your next budget period. The Data Management Branch/EIS in the Office of Policy for Extramural Research Administration, OER, NIH, will mail a computer-generated Face Page (Form Page 1) with an appropriate mailing label to the sponsoring institution approximately 4 months before the end of the current budget period. If a computer-generated Face Page is not received, call the Data Management Branch at (301) 435-0896. Using the mailing label provided, submit the completed, signed original application and two copies (with

required signatures) directly to the awarding component that is funding the award. Notify the Public Health Service (PHS) immediately if you do not intend to request continuation support. Application Form PHS 416-1 (revised 12/98) should be used to apply for support not previously recommended.

You may substitute computer generated facsimiles for any of the forms, except for the computer-generated Face Page. Substitute forms should be printed in black ink, and maintain the exact wording and format of the Government-printed forms, including all captions and spacing.

Please retain these instructions, which include sample form pages, for future submissions. Form pages have been printed separately, and are available from the applicant's office of sponsored research or from the Division of Extramural Outreach and Information Resources (DEOIR), (301) 435-0714, e-mail address: GrantsInfo@nih.gov. Forms can also be downloaded, in Adobe Acrobat format, from NIH's grants Web site at <http://www.nih.gov/grants/forms.htm>.

The NIH does not distribute any software for computer-generation of the application forms. Future developments in electronic transfer of applications will be published periodically in the *NIH Guide for Grants and Contracts*, <http://www.nih.gov/grants/guide>.

Use English only and avoid jargon and unusual abbreviations. Prepare the application, single-sided and single-spaced, and stay within the margin limitations indicated on the form.

The application must be clear and readily legible, and conform to the following three requirements:

- 1) The height of the letters must not be smaller than 10 point;

- 2) Type density must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi; and
- 3) No more than 6 lines of type must be within a vertical inch. Type requirements should be checked on the printed document using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/printer combination. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. The type size used throughout the application must conform to all three requirements.

Do not bind or staple the original. An incomplete or incorrectly prepared continuation application may result in a delay in award of funds.

II. PREPARING YOUR APPLICATION

A. Specific Instructions for Applicant (Part I)

Form Page 1

The computer-generated Face Page (Form Page 1), has information already preprinted through Item 6. Complete and use this as the final copy. Add the e-mail address information, if applicable. Check the preprinted material carefully and, when necessary, make corrections by entering the item number and the correct information under Item 11. Item 5, the Entity Identification Number (EIN) should be checked or supplied by the business official. The EIN number is assigned by the Department of Health and Human Services (DHHS) for payment and accounting purposes. The EIN number is not applicable for fellows at Federal laboratories.

(Note: If the preprinted copy is not provided or extensive corrections are necessary, use Form Page 1 in the form booklet.)

Items 7-8. Sponsor completes. See Part II.

Item 9. Training Site(s). Complete only if different from Item 4.

Item 10A. Permanent Mailing Address. If the information in Item 2a is not a permanent address, state the address where the applicant can always be contacted. **Changes should be reported promptly.**

Item 12. Applicant Certification and Acceptance.

Each application to the PHS requires that the following assurances and certifications be verified by the applicant's signature. Definitions are provided in the NIH and PHS Grants Policy Statements and in the PHS 416-1 application instructions.

Debarment and Suspension
Delinquent Federal Debt

In signing the application Face Page, the applicant certifies compliance with the assurances/certifications identified. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. Failure to sign Item 12 will preclude the possibility of an award.

Form Page 2

Item 13. Applicant Summary of Activities. Identify each item with its number and title. Do not exceed 3 pages for the entire summary.

Inclusion of Gender and Minority Study Subjects

Summarize the study population of the project as actually awarded in terms of planned sample size and the inclusion of participants by gender and ethnic minorities, using the table on Form Page 2.

Provide the number of male and female subjects enrolled in the study to date (cumulatively since the most recent competitive award), according to the categories below. If there is more than one study, provide a separate table for each study. Also report on the subpopulations included in the study.

Minority Group

A minority group is a readily identifiable subset of the U.S. population which is distinguished by either racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 defines racial and ethnic categories. NIH has chosen to continue the use of these definitions because they allow comparisons to many national databases, especially national health databases.

American Indian or Alaskan Native: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

Majority Group

White, not of Hispanic origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms “minority groups” and “minority subpopulations” are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

Subpopulation

Each minority group contains subpopulations which are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends of self-reporting of specific racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

B. Specific Instructions for Sponsor (Part II)

Form Page 1

Item 7. Human Subjects. Policy on research involving human subjects can be found in the NIH and PHS Grants Policy Statements or the PHS 416-1 application instructions.

If activities involving human subjects are **not** planned **at any time** during the proposed period of the fellowship, check “No.” The remaining parts of Item 7 are then not applicable.

If activities involving human subjects, whether or not exempt from Federal regulations for the protections of human subjects, are planned **at any time** during the proposed project period of the fellowship, check “Yes.” If the activities are designated to be exempt from the regulations, insert the exemption number(s) corresponding to one or more of the six exemption categories listed in the NIH and PHS Grants Policy Statements or the PHS 416-1. The remaining parts of Item 7 are then not applicable. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in the award. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category. In doubtful cases, consult with the program administrator in the awarding component or the Office for Protection from Research Risks (OPRR), National Institutes of Health, Rockville, MD 20892, (301) 496-7041, Web site — <http://www.nih.gov/grants/oprr/oprr.htm>.

If the planned activities involving human subjects are not exempt, complete the remaining parts of Item 7. If the sponsoring institution has an approved Multiple Project Assurance of Compliance on file with OPRR that covers the specific activity, insert the Assurance number and the latest date of approval by the Institutional Review Board (IRB) of the proposed activities. If the fellow will be participating in research supported by a research project grant for which IRB approval has already been obtained, insert the grant number(s) along with their IRB review date(s) and/or exemption designation(s). If space is insufficient in Item 7, enter “Item 15B” and provide additional information there. This date must not be earlier than one

year before the start date for which the application is submitted. **No application for continuation support should be submitted until the necessary certification of annual review has been obtained.**

Indefinite Project. If the sponsoring institution has an approved Assurance of Compliance on file with OPRR but, at the time of application, plans for the involvement of human subjects are so indefinite that IRB review and approval are not feasible, check "Yes" and insert "Indefinite." If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to the PHS awarding component.

Check the type of IRB review in the appropriate box. An IRB of an institution with a Multiple Project Assurance may review an application through expedited review procedure only if it complies with Section 46.110 of the human subject regulations 45 CFR 46.

Item 8. Vertebrate Animals

Policy on research activities involving vertebrate animals can be found in the NIH and PHS Grants Policy Statements or the PHS 416-1 application instructions.

If activities involving vertebrate animals are **not** planned **at any time** during the proposed project period, check "No." The remaining parts of Item 8 are then not applicable.

If activities involving vertebrate animals are planned **at any time** during the proposed project period, check "Yes." If the sponsoring institution has an approved Animal Welfare Assurance on file with OPRR, insert the Assurance identification number at Item 8b. In addition, **provide the latest date of approval** by the Institutional Animal Care and Use Committee (IACUC). In many instances, the fellow will be participating in research support by a research project grant for which the IACUC review has been obtained. This review is sufficient, provided the research would not be substantially modified by the participation of a fellow. The appropriate grant(s) must be identified along with the Assurance number and the IACUC review dates. If space is insufficient in Item 8, enter "Item 15B" and provide additional information there. **No application for continuation support should be submitted until the necessary verification of review has been obtained.**

Indefinite Project. If the sponsoring institution has an approved Animal Welfare Assurance on file with OPRR but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that IACUC review and approval are not feasible, check "Yes" and insert "Indefinite." If an award is made, vertebrate animals may **not** be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

Form Page 3

Item 14. Supplementation of Fellow. This refers to the provision of funds to the fellow by the institution in addition to the stipend provided by the fellowship award. By policy, no Federal funds may be used to supplement the awards unless explicitly authorized under the terms of the program from which such funds are to be derived.

Item 15. Comments of Sponsor

- A. Self-explanatory
- B. If the application involves human subjects or vertebrate animals and the Applicant Summary of Activities (Item 13) does not provide sufficient information to respond to the following instructions, provide the necessary information.

For research involving human subjects:

- (1) If the protocols planned for the coming year are different from those proposed in the last application, include an explanation of how they differ and check "Change." If they are not different, check "No Change"; and
- (2) If the protocols were not originally evaluated during competitive review, provide a brief description of their risk versus benefit to subjects and to the importance of the knowledge that may reasonably be expected to result, in accord with the DHHS regulations for protection of human subjects; and
- (3) Where appropriate, indicate whether children are involved in the study or how the study has relevance for conditions affecting children. (See PHS 416-1 Section III .A.1.c, for instructions concerning the Policy of Inclusion of Children.)

For research involving vertebrate animals:

If vertebrate animals were not involved in the last application but are to be included, or if significant changes regarding the use of animals are now proposed, provide a description of the intended involvement of animals in accord with the PHS policy for use of vertebrate animals in research and check "Change." Examples of significant changes might include substitution of one animal model for another or changing from noninvasive to invasive procedures. If there has been no change, check "No Change."

Item 16. Official Signing for Sponsoring Institution. Each application to the PHS requires that the following assurances and certifications be verified by the Official Signing for Sponsoring Institution. Definitions are provided in the NIH and PHS Grants Policy Statements and in the PHS 416-1 application instructions.

- Human Subjects
- Vertebrate Animals
- Debarment and Suspension
- Research Misconduct
- Civil Rights
- Handicapped Individuals
- Sex Discrimination
- Age Discrimination
- Financial Conflict of Interest

In signing the application, the duly authorized representative of the sponsoring institution certifies that the sponsoring institution will comply with all applicable assurances and certifications referenced above. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of an application, suspension and/or termination of an award, and debarment, as well as possible criminal penalties. The signer further certifies that the sponsoring institution will be accountable both for the use of any funds provided and for the performance of the grant supported project or activities resulting from this application.

This is the last page of the application.

Please number all page consecutively.